

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA *ex rel.*
ELLSWORTH ASSOCIATES, LLP,

Plaintiff-Relator,

v.

CVS HEALTH CORPORATION, *et al.*,

Defendants.

Case No.: 2:19-cv-02553-JMY

**RELATOR’S MEMORANDUM IN OPPOSITION TO DEFENDANTS’ MOTION TO
AMEND THE COURT’S ORDER UNSEALING THE SECOND AMENDED
COMPLAINT AND IN SUPPORT OF RELATOR’S CROSS MOTION THAT THE
COURT SET A RULE 16 CONFERENCE**

Relator filed its original Complaint under seal on June 12, 2019. While this matter remained under seal, Relator twice amended its complaint, ultimately filing the operative Second Amended Complaint (“SAC”) on March 28, 2022. Prior to filing the SAC, Relator redacted certain protected health information (“PHI”), pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its implementing regulations.¹ On May 6, 2022, the Court ordered that the SAC be unsealed and that Relator serve the SAC upon Defendants. ECF 21. Relator did so.

¹ In accordance with CMS guidance, Relator redacted from the SAC identifying information of certain SilverScript beneficiaries, including their names, addresses, telephone numbers, email addresses, social security numbers, health plan beneficiary numbers, pharmacy name and identifier, and prescription number. See U.S. Dep’t of Health & Human Servs., *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html> (last visited Oct 19, 2022).

Defendants move the Court to amend its unsealing Order and require Relator to produce an unfiled, unredacted draft of the SAC. Relator opposes the motion.

BACKGROUND

On September 28, 2022, more than two months after they had filed a 56-page Motion to Dismiss, Defendants sent Relator's counsel a draft of the motion at issue, stating it was their intention to ask the Court to amend the sealing Order unless Relator agreed to immediately provide them a copy of the SAC without any redactions. On October 4, 2022, Relator's counsel responded by stating that sharing the unfiled, unredacted SAC at this time would give Defendants an unfair head start on discovery, and countered Defendants' demand with two alternative proposals: (a) that Relator would provide an unredacted copy of the SAC along with all documents she or her counsel had in their possession concerning the allegations in exchange for the parties jointly requesting a Rule 16 conference and jointly initiating discovery, or (b) that Relator would provide an unredacted copy of the SAC conditioned on Defendants' agreement not to use it as part of their Motion to Dismiss briefing. Relator's counsel also explained that, if Defendants rejected these proposals and chose to file their motion, Relator would cross-move for the Court to set a Rule 16 conference and initiate discovery. That day, Defendants' counsel rejected the first proposal, but indicated that they wanted to discuss the second proposal with their client. The following day, on October 5, 2022, Defendants' counsel rejected the second proposal, as well. Thereafter, on October 6, 2022, Relator's counsel notified Defendants' counsel that, because they had rejected the suggestions for what Relator's counsel believed were reasonable compromises for access to the early discovery Defendants sought, Defendants should file their motion. Relator's counsel also reiterated that Relator intended to cross-move for the Court to set a Rule 16 conference and initiate discovery.

In support of their motion, Defendants adopt a peculiar reading of the Court’s May 6 Order. Rather than directing Relator to serve the as-filed SAC—as the Order states—Defendants assert that the Court actually directed Relator to serve an entirely different document: a draft of the unredacted SAC that was never filed. Thus, according to Defendants, Relator “is out of compliance” with the Court’s unsealing Order, even though Relator served the SAC as directed. Defs.’ Mem. (ECF 40-1) (“Mem.”) at 1.

Defendants raise two meritless arguments. *First*, Defendants claim (Mem. at 1) that the never-filed, unredacted SAC is a “judicial record that is presumptively accessible to Defendants.”² But a document that was never filed on the docket is not a judicial record, and Relator fully complied with the Court’s unsealing Order by serving the SAC exactly as it was filed with the Court. *Second*, Defendants argue (Mem. at 3-4) that it is “unclear” whether Relator disseminated information in violation of HIPAA, and Defendants “may have” an obligation to notify SilverScript enrollees about disclosures of PHI. These equivocal assertions—*i.e.*, that Defendants do not know whether Relator did anything wrong and do not know what they should do about it—fail to articulate any basis for relief. Likewise, their HIPAA argument is belied by the fact that Defendants rejected Relator’s offer to share the unredacted SAC.

² Even though they do not raise it as a separate ground for their motion, Defendants also suggest that they need the never-filed, unredacted SAC “to complete their investigation of Relator’s allegations, and possibly to complete the briefing on their motion to dismiss.” Mem. at 2. This argument rings hollow. If Defendants had a well-founded need to obtain a copy of the never-filed, unredacted SAC for the purpose of moving to dismiss the SAC, they would not have waited to bring this to the Court’s attention until over two months after filing their Motion to Dismiss. The fact that National Provider Identifiers (“NPIs”) were redacted from the SAC has been known to Defendants since the SAC was served on May 23, 2022. Given that they were able to file a 56-page Motion to Dismiss, Defendants evidently have had no difficulty mustering a defense in this matter.

Ultimately, Defendants seek to unilaterally and improperly benefit from one-sided discovery without incurring any discovery obligations themselves. However, Relator is cognizant of the Court's expectation that the parties will "conduct substantial discovery before the Rule 16 conference." Therefore, if the Court grants Defendants' motion, Relator separately cross-moves the Court to schedule the Rule 16 Conference and order that the discovery process begin for both parties.

ARGUMENT

A. Relator fully complied with the Court's unsealing Order.

Defendants falsely contend (Mem. at 1) that Relator has not "serv[ed] its own pleading." To the contrary, Relator has served the SAC on Defendants exactly as it was filed with the Court. What Defendants actually want is a separate document that was never filed on the docket. The Court's May 6 Order directed Relator to serve on Defendants the SAC, the United States' notices of election to decline intervention, and the unsealing Order itself. Relator complied with this Order by serving these documents on Defendants on May 23, 2022. The Order did not direct Relator to serve the never-filed, unredacted SAC Defendants now seek.

In tacit acknowledgement that their position is ungrounded in the text of the Court's unsealing Order,³ Defendants altogether omit that text from their motion. Instead, Defendants rely almost exclusively on *Purcell v. Gilead Sciences, Inc.*, 415 F. Supp. 3d 569 (E.D. Pa. 2019), for the proposition that they are entitled to "judicial records." However, *Purcell* is unavailing for two reasons. *First*, *Purcell* addressed whether a pleading may be kept under seal, an entirely separate question from whether Defendants are entitled to versions of the complaint that have never been

³ Tellingly, even though they contend Relator is "out of compliance" with the Order (Mem. at 1), Defendants request that the Court *amend* its unsealing Order, not enforce the Order it already issued.

filed. *Second*, the document Defendants seek—*i.e.*, the never-filed, unredacted SAC—is not itself a judicial record.

In *Purcell*, the relators filed three iterations of the complaint under seal. *Purcell*, 415 F. Supp. 3d at 572. The original complaint had named only a single corporate defendant. *Id.* The first amended complaint then added seventeen individual doctors as defendants. *Id.* After a change of counsel, the relators apparently “reconsidered a good faith basis” to name the individual doctors as defendants, *id.* at 577, and filed a second amended complaint dropping their claims against the doctors, *id.* at 572. After the government declined to intervene in the case, the court ordered that the second amended complaint be unsealed, which the relators did not oppose. *Id.* at 572. However, the relators sought to keep the first amended complaint under seal to protect the identities of the seventeen defendants who had been removed from the case. *Id.* at 572-73. The court held that the first amended complaint should be unsealed, but because the court was “concerned with publicly revealing the names of” the nonparty doctors, permitted the relators to redact the names of the doctors before the complaint was unsealed and served upon the defendant. *Id.* at 577.

Purcell, therefore, addressed the entirely separate question of whether a pleading that has been filed with the court may still be kept under seal. By contrast, here the document Defendants seek has not been filed under seal; it has never been filed at all. Because the unfiled SAC Defendants seek has neither been “filed with the court” nor “incorporated or integrated into” the Court’s “adjudicatory proceedings,” it is not a judicial record to which a presumptive right of access applies. *See In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019); *see also Bond v. Utreras*, 585 F.3d 1061, 1073 (7th Cir. 2009) (judicial records do not include discovery documents “not filed with the court”). Moreover, even though the court in *Purcell* ordered the complaint to be unsealed, it still permitted the relators to redact certain

information before the complaint was made public and served on the defendant. If anything, then, *Purcell* contradicts Defendants’ argument that they have an unfettered right to an unfiled draft of the SAC.

Fundamentally, Defendants’ judicial records argument proves too much. If the unredacted, never-filed SAC were a judicial record, Defendants should seek to have it filed on the open court docket to ensure public access. *F.T.C. v. AbbVie Prods. LLC*, 713 F.3d 54, 62 (11th Cir. 2013) (“The common-law right of access ‘establish[es] a general presumption that criminal and civil actions should be conducted publicly’” (quoting *Chi. Trib. Co. v. Bridgestone/Firestone, Inc.*, 263 F.3d 1304, 1311 (11th Cir. 2001))); *see also Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988) (“Access means more than the ability to attend open court proceedings; it also encompasses the right of the public to inspect and to copy judicial records.”). Defendants, however, are not seeking public access to the unredacted SAC. Instead, Defendants believe “that enrollee privacy should be protected on the public docket” (Mem. at 3), and insist the Court should order the never-filed, unredacted SAC be disclosed not on the docket, but only to them (*id.* at 4). It thus is clear that Defendants are not seeking access to judicial records at all, but instead are requesting the Court order Relator to provide document discovery as required under Fed. R. Civ. P. 26(a)(1) (initial disclosures). But, under Rule 26(a)(1)(C), discovery is not to begin until “at or within 14 days after the parties’ Rule 26(f) conference unless a different time is set by stipulation or court order.” The Court has not yet ordered that the parties hold a Rule 26(f) conference or set a different time for the parties to present their discovery plan.

B. Defendants’ ill-formed HIPAA concerns are not a basis for relief.

Defendants’ amorphous HIPPA concerns do not entitle them to the never-filed, unredacted SAC. Defendants do not assert that in fact any HIPAA violations have taken place or that they actually have any notification obligations. Rather, Defendants suggest only that “[i]t is a *potential*

improper disclosure *if* an alleged whistleblower discloses PHI to other persons not identified in [45 C.F.R.] § 164.502(j),” “[i]t is *unclear* to Defendants whether 45 C.F.R. § 164.502(j) applies in connection with” Relator’s alleged disclosure of PHI, and Defendants “*may* have an[] obligation” to notify SilverScript enrollees as to the disclosure of PHI. Mem. at 3-4 (emphasis added). Yet redacting PHI from the SAC is exactly what Relator was supposed to do to comply with HIPAA, and Defendants have failed to articulate how any other HIPAA violation has occurred. Furthermore, Defendants have failed to articulate how getting access to the unredacted SAC is necessary for them to determine if any HIPAA violations have occurred. Unsurprisingly, Defendants have failed to provide any legal basis under which their equivocation entitles them to the extraordinary remedy of unilateral discovery—let alone whether an actual, articulable HIPAA violation would justify their request.

This is not the first time Defendants have accused Relator of unsubstantiated legal violations. On June 16, 2022, counsel for Defendants sent Relator’s counsel a “Demand for Return of Property,” baselessly arguing that Relator’s retention of certain documents in an effort to abate Defendants’ fraud constituted a violation of her employment agreement and “conversion of company property.” Demand Letter (June 16, 2022), Exhibit A. Relator’s counsel explained that “because Ms. Miller retained only a small subset of documents from CVS necessary to pursue a *qui tam* lawsuit, her actions are protected by federal law.” See Response to Defendants’ Counsel Demand Letter (June 20, 2022), Exhibit B.

On August 2, 2022, Defendants’ counsel again accused Relator of impropriety, informing Relator’s counsel that Relator improperly shared HIPAA confidential information with rev.com, a vendor used to transcribe audio recordings. On August 16, 2022, Relator’s counsel provided an opinion of outside counsel that neither Relator nor her counsel were required to have entered into

a Business Associate Agreement with the vendor rev.com, and that rev.com had provided adequate assurances of the “technical, administrative, and physical safeguards required to protect the confidentiality, integrity, and availability of the data.” *See* Opinion of HIPAA Counsel (August 15, 2022), Exhibit C. As such, there had been no violation of HIPAA.

Now again, Defendants are attempting to use the guise of inchoate HIPAA concerns to get an improper head start on discovery. Defendants say nothing concerning their prior, unsubstantiated attempts to do so, and suggest, almost entirely without argument, that HIPAA and its implementing regulations require Relator to unilaterally provide discovery material. They do not.

Additionally, Defendants’ suggestion that Relator may have taken information from CVS without meeting a legal exception is simply unfounded. Pursuant to the HIPAA Privacy Rule, a covered entity is not considered to have violated HIPAA if one of its employees discloses PHI to an attorney based on a good-faith belief that the entity has engaged in unlawful conduct. 45 C.F.R. § 164.502(j)(1). Nor is such a disclosure considered a “breach” that would require Defendants to notify their beneficiaries. *See id.* §§ 164.404(a)(1) (requiring notification “following the discovery of a breach” of PHI), 164.402(1)(i) (breach does not include protected disclosure under § 164.502).

Although they couch their request as fulfilling a notification obligation under HIPAA, Defendants’ real motive is apparent. Had they actually been motivated to ensure they were providing required HIPAA notice, Defendants would have agreed to Relator’s proposal that it would share the unredacted SAC (under the condition that the unredacted SAC would not be used in Defendants’ Motion to Dismiss briefing). But they rejected this proposal, making clear that Defendants are seeking one-sided discovery which they intend to use in their Motion to Dismiss briefing—and, perhaps, to bring unfounded, retaliatory litigation regarding Relator’s retention of

company documents. Moreover, if Defendants required the information they desire to adequately respond to the SAC, Defendants would have sought this discovery material as soon as they were served with the as-filed SAC, not two months after filing their Motion to Dismiss.

C. If the Court grants Defendants’ motion, it should enter an order for a Rule 16 Conference.

Defendants have requested that the Court order Relator to produce discovery material in the form of a document that has not been filed on the docket. It would be fundamentally unfair to impose discovery obligations on only one party. If Relator is ordered to produce the unredacted SAC, because the unredacted SAC would be subject to the rules of bilateral discovery, Relator believes the discovery process ought to begin as soon as possible. Relator also understands the Court’s policy is that the parties should “conduct substantial discovery before the Rule 16 conference.” U.S. District Judge John Milton Younge, *Policies and Procedures: General Matters, Civil Cases, and Criminal Cases* at 9. Therefore, if the Court grants Defendant’s motion, Relator respectfully requests that the Court enter an order setting the Rule 16 conference and directing the parties to commence discovery immediately and to “conduct substantial discovery before the Rule 16 conference.” *Id.*

Dated: October 20, 2022

/s/ W. Scott Simmer
W. Scott Simmer (*pro hac vice*)
William G. Powers (PA Bar No. 316876)
Jennifer Fountain Connolly (*pro hac vice*)
Noah M. Rich (*pro hac vice*)
Catherine H. Dorsey (*pro hac vice*)
BARON & BUDD, P.C.
The Watergate
600 New Hampshire Ave. NW,
10th Floor
Washington, DC 20037
Telephone: (202) 333-4562
Facsimile: (202) 337-1039

Counsel for Relator Ellsworth Associates, LLP

CERTIFICATE OF SERVICE

I certify that on October 20, 2022, this document was filed electronically, that it is available for viewing and downloading from the ECF system, and that all counsel of record will be served by the ECF system.

/s/ W. Scott Simmer